UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,935	08/21/2003	Ivan Lieberburg	08576.0047-00	7376

26694 7590 08/20/2007

VENABLE LLP
P.O. BOX 34385
WASHINGTON, DC 20043-9998

EXAMINER	
SOROUSH, ALI	
ART UNIT	**PAPER NUMBER**
1616	
MAIL DATE	**DELIVERY MODE**
08/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/644,935	LIEBERBURG, IVAN	
	Examiner	Art Unit	
	Ali Soroush	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *16-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Receipt

Applicant's response filed 05/14/2007 in response to Office Action mailed on 02/01/2007 is acknowledged.

Status of Claims

Claims 1, 6, and 11 have been amended and claims 16-31 have been withdrawn. Therefore claims 1-15 are currently pending examination on patentability.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15 were rejected under 35 U.S.C. 102(b) as being anticipated by Elan Pharma (Zonisamide, Approvable Labeling, Published 03/27/2000). In light of Applicants amendment submitted with aforementioned response the rejection is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-15 are are rejected under 35 U.S.C. 103(a) as being unpatentable over Elan Pharma (Zonisamide Approvable Labeling, Published 03/27/2000) in view of Iliopoulou et al. (Acute Pancreatitis Due to Captopril Treatment, Disgestive Diseases and Sciences, Vol. 49 No. 9, pp. 1882-1883, Published 09/2001).

Applicant Claims

Applicant claims a method of improving safety, managing health, and ameliorating adverse side effects in a patient receiving zonisamide treatment for epileptic seizures by informing the patient that pancreatitis is a potential side effect and to seek immediate medical attention should the patient experience one or more symptoms associated with pancreatitis.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Elan Pharma teaches, "**Zonegran™ (zonisamide) is an antiseizure drug** chemically classified as a sulfonamide and unrelated to other antiseizure agents." (See

page 1, Lines 3-4). "**Zonegran** is supplied for oral administration **as capsules** containing **100 mg zonisamide**." (See page 1, Lines 10-11). "Start with one Zonegran capsule each day (100 mg). Swallow the capsule whole." (See page 23, Line 4). "After a week or so, your doctor may increase your dose of Zonegran. This may occur more than once. It is done to get the best control for your seizures. Take only the number of Zonegran capsules you were told to take." (See page 23, Lines 6-8). Elan Pharma further teaches, "The most **commonly observed adverse events associated with the use of Zonegran** in controlled clinical trials that were not seen at an equivalent frequency among placebo-treated patients were somnolence, **anorexia**, dizziness, headache, **nausea**, and agitation/irritability." (See page 14, Lines 14-17). "**Contact your doctor right away if**: ... **you develop** signs of kidney stones (sudden back pain, **abdominal pain**, blood in your urine) ..." (See page 24, Lines 5-9).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Elan Pharma does not teach informing the patient that pancreatitis is a potential side effect of zonisamide treatment. Iliopoulou et al. cure this deficiency.

Iliopoulou et al. teaches that there are **drugs** that **can cause acute pancreatitis**. (See page 1882, Column 1, Lines 30-31). "The most **frequently incriminated drugs** are **sulfonamide derivatives**, valproic acid ..." (See page 1882, column 1, Line 31 and column 2, Lines 1-2).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Elan Pharma and Iliopoulou et al. One would have been motivated to do so because Elan Pharma teaches that zonisamide is a sulfonamide class of drug and Iliopoulou et al. teaches that this class of drugs are known frequently to cause acute pancreatitis. Therefore, if one wanted to inform a patient of all the adverse side effects associated with zonisamide one would inform them of the potential for acute pancreatitis as this has been implicated in similar drugs of the sulfonamide class. Further because Elan Phrama teaches that one taking zonisamide should seek immediate medical attention in the case of sudden back pain or abdominal pain, which are also symptoms of pancreatitis, it would have been obvious that a patient would seek medical attention upon experiencing these symptoms and then a medical practitioner would perform the necessary tests to determine if pancreatits is the proper diagnosis. Therefore, the improvement of the information provided the patient to include pancreatitis would have been obvious to one of ordinary skill in the art in view of the teachings of Iliopoulou et al. For the foregoing reasons the instant methods would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number For the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush
Patent Examiner
Art Unit: 1616

Johann Richter
Supervisory Patent Examiner
Technology Center 1600